REMARKS

By this Amendment, claims 4 and 10 are cancelled, and the specification and claims 1-3, 5, 6, and 11-13 are amended. The specification is amended solely to conform it to the format preferred by the Office for recitation of trademarks. The claims are amended to address the issues raised in the Office Action and to correct typographical errors. Support for the amendments to the claims comes from the specification, as originally filed. No new matter is added by the amendments to the specification and claims. Currently, claims 1-3, 5-9, and 11-16 are pending, all but claims 1-3, 5, 6, and 9-14 having been withdrawn by the Examiner as directed to non-elected inventions.

I. *Restriction Requirement*

The Office indicates that the arguments presented by Applicant in the paper filed July 24, 2002, have been considered, but deemed unpersuasive. (Office Action at paragraph 2.) The Office therefore makes the Restriction Requirement FINAL. Applicant respectfully traverses the Restriction Requirement, reasserts the arguments presented in the response filed July 24, 2002, and requests that the Office reconsider and withdraw the Restriction Requirement. In the event that the Office does not withdraw the Restriction Requirement, Applicant reserves the right to pursue the subject matter recited in the non-elected claims in one or more divisional applications.

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202.408.4000
Fax 202.408.4400
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II. *Trademarks*

The Office objects to the format used by Applicant to recite the trademarks ROMPUN® and IMALGENE 1000®. By this Amendment, the specification at page 4 has been amended to recite ROMPUN® and IMALGENE 1000®. The specification at page 4 clearly indicates that ROMPUN® is the trade name for the anesthetic drug xylazine. Furthermore, the specification at page 4 clearly indicates that IMALGENE 1000® is the trade name for the anesthetic drug ketamine. Applicant submits that the specification now properly identifies these trademarks. Therefore, Applicant respectfully requests that the Office reconsider and withdraw the objection to the specification relating to recitation of ROMPUN® and IMALGENE 1000®.

III. *Rejections Under 35 U.S.C. § 112, Second Paragraph*

The Office rejects claims 1-5 and 10-13 under 35 U.S.C. § 112, second paragraph as indefinite. (Office Action at paragraph 7.) By this Amendment, claims 4 and 10 are cancelled, rendering the rejections moot as they apply to those claims. Applicant respectfully traverses the rejections as they apply to claims 1-3, 5, and 11-13, and submits that the presently claimed invention satisfies the requirements of 35 U.S.C. § 112, second paragraph.

The Office rejects claims 1-3, 5, and 11-13 as indefinite for recitation of the phrase "active principle". The Office asserts that a principle is not an art-recognized term. Applicant respectfully submits that a term does not have to be an art-recognized term for it to be clear and definite. In the present case, it would be clear to one of skill in the art that the "active principal" indicates a compound, either chemical or biological, that induces an irreversible inactivation or degradation of a collagen receptor on

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thrombocytes. One of skill in the art would understand that any substance that has this characteristic would be included within the claimed term. Accordingly, Applicant submits that the term is not indefinite or unclear to those of skill in the art. For at least this reason, Applicant respectfully requests that the Office reconsider and withdraw the rejection of claims 1-3, 5, and 11-13 for recitation of "active principle".

The Office further rejects claim 1 as indefinite for reciting "degradation". Applicant submits that there is no requirement that the claims recite the specific mechanism of action of a claim term. Furthermore, in view of the present specification at, for example, page 9, line 14 to page 10, line 21, it would be clear to one of skill in the art what is meant by "degradation". For at least this reason, Applicant respectfully submits that the term "degradation" is clear and definite. Therefore, Applicant respectfully requests that the Office reconsider and withdraw the rejection of claim 1 as indefinite for reciting "degradation".

The Office rejects claims 3, 5, 13, and 14 as indefinite for recitation of "JAQ1". Applicant respectfully submits that an applicant is entitled to be his own lexicographer as long as the term used is defined in the present specification and is not repugnant to those of skill in the art. MPEP § 2173.05(a). The present specification at page 3, line 17-21, for example, indicates that JAQ1 is a monoclonal antibody that is secreted by the hybridoma cell line DSM ACC 2487. Applicant submits that, in view of the disclosure of the specification, one of skill in the art would know what was meant by "JAQ1". Furthermore, Applicant submits that use of this term in the claims and the specification is not repugnant to any definition known in the art. Therefore, Applicant submits that the use of the term "JAQ1" is clear and definite. Applicant respectfully requests that the Office reconsider and withdraw the rejection of claims 3, 5, 13, and 14.

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1300 I Street, NW
Washington, DC 20005
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The Office rejects claim 10 for grammatical reasons. By this Amendment, claim 10 is cancelled, rendering the rejection moot.

In view of the above comments and the amendments to the claims, Applicant submits that present claims 1-3, 5, and 11-13 satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicant respectfully requests that the Office reconsider and withdraw the rejection of these claims under this statute.

IV. *Rejections Under 35 U.S.C. § 112, first paragraph*

A. Enablement

The Office rejects claims 3, 5, 9, 10, 13, and 14 under 35 U.S.C. § 112, first paragraph as not enabled. (Office Action at paragraph 9). Specifically, the Office asserts that the monoclonal antibody JAQ1 is required to practice the claimed invention, but that a deposit satisfying U.S. PTO rules has not yet been made. By this Amendment, claim 10 is cancelled, rendering the rejection as it applies to that claim moot.

Applicant affirms that the statement made on page 3, lines 19-22, of the present specification is accurate. That is, the hybridoma cell line secreting JAQ1 has been deposited under DSM ACC 2487 at the DSM in Germany in accordance with the Budapest Treaty. Applicant further affirms that a Deposit Declaration made in accordance with U.S. PTO rules will be submitted in this application prior to issuance of the application as a U.S. patent. Accordingly, Applicant requests that the Office hold this enablement rejection in abeyance until the Deposit Declaration is submitted.

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Washington, DC 20005
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B. Scope of Enablement

The Office rejects claims 1-5 and 10-13 under 35 U.S.C. § 112, first paragraph as not enabled for the full scope of the claims. (Office Action at paragraph 10.) In particular, the Office asserts that the claims are only enabled for the JAQ1 antibody specifically binding to GPVI for diagnostic assays. By this Amendment, claims 4 and 10 are cancelled, rendering the rejection as it applies to those claims moot. Applicant respectfully traverses the rejection as it applies to claims 1-3, 5, and 11-13.

The Office asserts that the specification does not provide sufficient information for one of skill in the art to make any active principal having the recited characteristics. Applicant respectfully disagrees. It is well known to those of skill in the art that, once an antibody having a specific binding characteristic is obtained, it can be used to identify multiple other substances that have the same binding characteristic. For example, those of skill in the art immediately recognize that anti-idiotype antibodies can be raised against the original antibody, and that these anti-idiotype antibodies can be used to rapidly and easily identify numerous other substances having three-dimensional structures similar or identical to the original antibody binding site. Combinatorial chemistry and high throughput screening are standard techniques used in the art, and one of skill in the art would know to apply these techniques to develop active principals according to the present claims. Making such active principals is thus well within the skill of those of skill in the art, and does not represent undue or excessive experimentation.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 1-3, 5, and 11-13 as not enabled for the full scope of the claims.

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1300 I Street, NW
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The Office also asserts that the claims are not enabled for protection against all thrombotic diseases because the field of treatment of thrombotic diseases is unpredictable. While not necessarily agreeing with the Office on this position, in order to expedite allowance of the claims, by this Amendment Applicant has amended claim 1 to recite that the medicament protect against thrombotic diseases involving platelet collagen receptor glycoprotein VI (GPVI). Claim 11 likewise recites this characteristic. Applicant submits that the information presented in the present specification is more than sufficient to enable the present claims. For at least this reason, Applicant respectfully requests that the Office reconsider and withdraw this aspect of the rejection.

For at least the reasons discussed above, Applicant submits that claims 1-3, 5, and 11-13 are fully enabled by the present specification. Therefore, Applicant respectfully requests that the Office reconsider and withdraw the rejection of these claims under 35 U.S.C. § 112, first paragraph, as not enabled.

C. Written Description

The Office rejects claims 1-5 and 10-13 under 35 U.S.C. § 112, first paragraph, as failing to be supported by an adequate written description. (Office Action at paragraph 11.) More specifically, the Office asserts that, at the time of filing this application, Applicant was not in possession of any medicament other than one comprising the JAQ1 antibody. By this Amendment, claims 4 and 10 are cancelled, rendering the rejection as it applies to those claims moot. Applicant traverses the rejection as it applies to claims 1-3, 5, and 11-13.

The Office appears to believe that 35 U.S.C. § 112, first paragraph, requires an applicant to be in physical possession of every species and every embodiment encompassed by claims in the application. Applicant respectfully submits that there is

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1300 I Street, NW
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no such requirement in 35 U.S.C. § 112, first paragraph. The purpose of the written description requirement of 35 U.S.C. § 112, first paragraph, is to ensure that an applicant does not claim an invention that was not contemplated at the time of filing the application. See MPEP § 2163. Possession of a claimed invention can be shown in a variety of ways. It is not necessary that an applicant be in physical possession of all species encompassed by a generic claim. Rather, it is sufficient that an applicant describe the genus using distinguishing identifying characteristics sufficient to distinguish the claimed invention from other, unclaimed subject matter, thus showing that the applicant was in possession of the invention. MPEP § 2163.

In the present application, Applicant has identified antibody JAQ1, which binds specifically to GPVI, resulting in its inactivation or degradation. As discussed above, with this information, one of skill in the art would immediately recognize that the antigen binding region of the antibody is the structure responsible for the binding. As discussed above, it would be immediately apparent that this structure could be replicated by other substances having the same three dimensional structure (and that could be identified without undue experimentation). Thus, disclosure of a single working example, the JAQ1 antibody, adequately describes the entire genus of active principals encompassed by the claims. Therefore, Applicant submits that there is an adequate written description of the genus of active principals recited in the claims.

For at least the reason discussed above, Applicant submits that present claims 1-3, 5, and 11-13 find adequate written description in the present specification. Accordingly, Applicant respectfully requests that the Office reconsider and withdraw the rejection of these claims under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description.

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V. *Rejections Under 35 U.S.C. § 102*

A. Nieswandt *et al.*

The Office rejects claims 1-4 and 9-13 under 35 U.S.C. § 102(a) [*sic* § 102(b)] as anticipated by Nieswandt *et al.* (J. Biol. Chem. 2000). (Office Action at paragraph 13.) The Office asserts that Nieswandt *et al.* discloses monoclonal antibody JAQ1 and a method of making it, and thus anticipates claims 1-4 and 9-13. By this Amendment, claims 4 and 10 are cancelled, rendering the rejection moot as it applies to those claims. Applicant respectfully traverses the rejection as it applies to claims 1-3, 9, and 11-13.

Claims 1-3, 5, 6, 9, and 11-14 are currently under examination in this application. Of those claims, claims 1, 6, 9, and 11 are independent. If an independent claim is not anticipated by a reference, then its dependent claims cannot be anticipated because, by definition, dependent claims include all of the elements or steps of the claim(s) from which they depend. Thus, if independent claims 1, 9, and 11 are not anticipated by Nieswandt *et al.*, then claims 2, 3, 5, 6, and 12-14 are not anticipated either.

Present claim 1 recites a medicament that is in the form of a physiologically acceptable injection. Nieswandt *et al.* does not disclose such a medicament. Accordingly, Nieswandt *et al.* does not anticipate independent claim 1 or dependent claims 2, 3, and 5.

Present claim 6 recites a diagnostic agent that is in the form of a physiologically acceptable injection. Nieswandt *et al.* does not disclose such a diagnostic agent. Accordingly, Nieswandt *et al.* does not anticipate independent claim 6 or dependent claim 14.

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Present claim 9 recites hybridoma cell line DSM ACC 2487. Nieswandt *et al.* does not disclose this cell line. Accordingly, claim 9 is not anticipated by Nieswandt *et al.*

Present claim 11 recites a method for producing a medicament comprising providing at least one active principal and combining the principal with a physiological carrier. Nieswandt *et al.* does not disclose such a method. Accordingly, independent claim 11 and dependent claims 12 and 13 are not anticipated by Nieswandt *et al.*

For at least the reasons set forth above, Applicant submits that claims 1-3, 5, 6, 9, and 11-14 are not anticipated by Nieswandt *et al.* Therefore, Applicant requests that the Office reconsider and withdraw the rejection of these claims under 35 U.S.C. § 102(a) as anticipated by Nieswandt *et al.*

B. Clemetson *et al.*

The Office rejects claims 1, 2, 4, and 11 under 35 U.S.C. § 102(b) as anticipated by Clemetson *et al.* (J. Biol. Chem. 1999). (Office Action at paragraph 14.) The Office asserts that Clemetson *et al.* discloses a medicament comprising antibodies against GPVI and a method of making it, and thus anticipates claims 1, 2, 4, and 11. By this Amendment, claim 4 is cancelled, rendering the rejection moot as it applies to that claim. Applicant respectfully traverses the rejection as it applies to claims 1, 2, and 11.

Present claim 1 recites a medicament that is in the form of a physiologically acceptable injection. Clemetson *et al.* does not disclose such a medicament. Accordingly, Clemetson *et al.* does not anticipate independent claim 1 or dependent claim 2.

Present claim 11 recites a method for producing a medicament comprising providing at least one active principal and combining the principal with a physiological

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carrier. Applicant submits that Clemetson *et al.* does not disclose such a method. Accordingly, independent claim 11 is not anticipated by Clemetson *et al.*

For at least the reasons set forth above, Applicant submits that claims 1, 2, and 11 are not anticipated by Clemetson *et al.* Therefore, Applicant requests that the Office reconsider and withdraw the rejection of these claims under 35 U.S.C. § 102(a) as anticipated by Clemetson *et al.*

C. Buchanan *et al.*

The Office rejects claim 1 under 35 U.S.C. § 102(b) as anticipated by Buchanan *et al.* (Thrombosis Research 1983). (Office Action at paragraph 15.) The Office asserts that Buchanan *et al.* discloses a medicament comprising aspirin, which inhibits collagen-induced platelet aggregation, and thus anticipates claim 1. Applicant respectfully traverses this rejection.

Present claim 1 recites a medicament that is in the form of a physiologically acceptable injection. Buchanan *et al.* does not disclose such a medicament. Accordingly, Buchanan *et al.* does not anticipate independent claim 1.

For at least the reason set forth above, Applicant submits that claim 1 is not anticipated by Buchanan *et al.* Therefore, Applicant requests that the Office reconsider and withdraw the rejection of this claim under 35 U.S.C. § 102(b) as anticipated by Buchanan *et al.*

VI. *Rejections Under 35 U.S.C. § 103*

A. Nieswandt *et al.* in view of Owens *et al.*

The Office rejects claims 1 and 5 under 35 U.S.C. § 103(a) as unpatentable over Nieswandt *et al.* (J. Biol. Chem. 2000) in view of Owens *et al.* (J. Immunol. Methods

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1994). (Office Action at paragraph 17.) The Office relies on Nieswandt *et al.* for the disclosure discussed above. The Office relies on Owens *et al.* as a teaching of the modification of murine antibodies, such as humanized antibodies. The Office concludes that it would have been obvious to produce the antibodies of Nieswandt *et al.* as humanized antibodies using the teaching of Owens *et al.* because humanized antibodies are used in therapy in humans because they are less likely to induce an immune response. Applicant traverses this rejection.

Among the numerous requirements for a *prima facie* case of obviousness, one is that the combination of references relied upon by the Office to reject the claims must teach each and every element or step in the rejected claims. Applicant submits that this requirement has not been met by the rejection set forth in the Office Action.

As discussed above, Nieswandt *et al.* does not disclose a medicament in the form of a physiologically acceptable injection. Further, Nieswandt *et al.* does not suggest such a medicament. Owens *et al.* fails to provide this missing element. As such, the combination of Nieswandt *et al.* and Owens *et al.* fails to teach each and every limitation of claim 1. Thus, the combination fails to render claim 1 and its dependent claim 5, obvious.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 1 and 5 under 35 U.S.C. § 103(a) as unpatentable over Nieswandt *et al.* in view of Owens *et al.*

B. Nieswandt *et al.* or Clemetson *et al.* in view of U.S. Patent No. 6,406,888

The Office rejects claim 6 under 35 U.S.C. § 103(a) as unpatentable over Nieswandt *et al.* (J. Biol. Chem. 2000) or Clemetson *et al.* (J. Biol. Chem. 1999) in view of U.S. Patent No. 6,406,888. (Office Action at paragraph 18.) The Office relies on

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Nieswandt *et al.* and Clemetson *et al.* for the disclosures discussed above. The Office relies on the '888 patent as a teaching of linking antibodies to other compounds, including diagnostic agents and labels, to target the compounds to cells. The Office concludes that it would have been obvious to label the antibodies of Nieswandt *et al.* or Clemetson *et al.* based on the teaching of the '888 patent, and use the labelled antibodies as diagnostic agents. Applicant traverses this rejection.

As mentioned above, a *prima facie* case of obviousness requires that the combination of references relied upon by the Office to reject the claims must teach each and every element or step in the rejected claims. Applicant submits that this requirement has not been met by the rejection set forth in the Office Action.

As discussed above, Nieswandt *et al.* does not disclose a diagnostic agent in the form of a physiologically acceptable injection. Further, Nieswandt *et al.* does not suggest such a diagnostic agent. Likewise, Clemetson *et al.* fails to disclose or suggest such a diagnostic agent. The '888 patent fails to provide this missing element. As such, the combinations of Nieswandt *et al.* and the '888 patent, and of Clemetson *et al.* and the '888 patent, fail to teach each and every limitation of claim 6. Thus, the combinations fail to render claim 6 obvious.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claim 6 under 35 U.S.C. § 103(a) as unpatentable over Nieswandt *et al.* (J. Biol. Chem. 2000) or Clemetson *et al.* (J. Biol. Chem. 1999) in view of U.S. Patent No. 6,406,888.

C. Clemetson *et al.* in view of Harlow

The Office rejects claims 11 and 12 under 35 U.S.C. § 103(a) as unpatentable over Clemetson *et al.* in view of Harlow (Antibodies: A Laboratory Manual 1988).

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Washington, DC 20005
202.408.4000
Fax 202.408.4400
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(Office Action at paragraph 19.) The Office relies on Clemetson *et al.* for the disclosure discussed above. The Office relies on Harlow as a teaching of methods for producing monoclonal antibodies. The Office concludes that it would have been obvious to combine the teachings of Clemetson *et al.* and Harlow to produce the monoclonal antibodies according to the present claims. Applicant traverses this rejection.

As mentioned above, a *prima facie* case of obviousness requires that the combination of references relied upon by the Office to reject the claims must teach each and every element or step in the rejected claims. Applicant submits that this requirement has not been met by the rejection set forth in the Office Action.

As discussed above, Clemetson *et al.* does not disclose a method for producing a medicament comprising providing at least one active principal and combining the principal with a physiological carrier. Further, Clemetson *et al.* does not suggest such a method. Harlow fails to disclose or suggest such a method. Thus, Harlow fails to provide an element missing from Clemetson *et al.* that is needed to achieve present claim 11. As such, the combination of Clemetson *et al.* and Harlow fails to teach each and every limitation of claim 11 and its dependent claim 12. Thus, the combination fails to render claims 11 and 12 obvious.

For at least this reason, Applicant requests that the Office reconsider and withdraw the rejection of claims 11 and 12 under 35 U.S.C. § 103(a) as unpatentable over Clemetson *et al.* in view of Harlow.

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HENDERSON
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GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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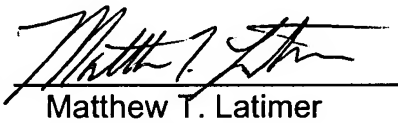
VII. *Conclusion*

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application, and the timely allowance of the pending claims.

Please grant any extension of time required to enter this Amendment that is not attached hereto, and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: 

Matthew T. Latimer
Reg. No. 44,204
571-203-2714
matthew.latimer@finnegan.com

Date: April 21, 2003

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

APPENDIX
(Accompanying Amendment of April 21, 2003)

U.S. Patent Application No. 10/051,168

IN THE SPECIFICATION

Page 3, amend the paragraph bridging lines 13-22 as follows:

Based on these results, is has now been found that a medicament is effective against thrombotic diseases if it comprises an active [principle] principal that induces an irreversible inactivation or degradation of a collagen receptor on thrombocytes. This active [principle] principal may be a chemical compound or a monoclonal or polyclonal antibody. A preferred monoclonal antibody is JAQ1 and the preferred collagen receptor is platelet GPVI. If the monoclonal antibody JAQ1 is used it should be a humanized monoclonal antibody JAQ1. The hybridoma cell line secreting JAQ1 has been deposited under DSM ACC 2487 at the Deutsche Sammlung von Microorganismen und Zellkuturen GmbH in Braunschweig in accordance with the Budapest Treaty.

Page 4, amend the paragraph bridging lines 26-35 as follows:

Chemicals. Anesthetic drugs xylazine [(Rompun®)] (ROMPUN®) and ketamine [(Imalgene 1000®)] (IMALGENE 1000®) were delivered from Bayer (Leverkusen, Germany) and Mérial (Lyon, France), respectively. Immobilized papain (Pierce, Rockford, IL, USA), high molecular weight heparin, ADP, phorbol-12-myristate-13-acetate (PMA), (all from Sigma Deisenhofen, Germany), FITC-labeled Annexin V (Boehringer Mannheim, Germany), and collagen (Kollagenreagent Horm, Nycomed, Munich, Germany) were purchased. CRP (GKO-$(GPO)_{10}$-GKOG) (single letter amino acid code where O=hydroxyproline) and convulxin were kindly provided by S.P. Watson

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1300 I Street, NW
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(Oxford, U.K.) FITC-labeled convulxin was a generous gift from M. Jandrot-Perrus (Paris, France).

Page 18, amend the paragraph bridging lines 15-23 as follows:

Thus, it is an object of the present invention to provide a medicament for the protection against thrombotic diseases which comprises an active [principle] principal, preferably an antibody, against a platelet collagen receptor that not only blocks, but irreversibly depletes the target receptor. Such a monoclonal antibody is defined by its binding to the same or a similar epitop of the collagen receptor for thrombocytes as the monoclonal antibody JAQ1. Preferably, as antibody the monoclonal antibody JAQ1 should be used. The preferred collagen receptor is platelet GPVI. Most preferred is a medicament which contains the respective humanized monoclonal antibody for protection [againts] against thrombotic diseases.

IN THE CLAIMS:

Please amend claims 1-3, 5, 6, and 11-13 as follows:

1. (Twice Amended) A medicament for protection against thrombotic diseases involving platelet collagen receptor glycoprotein VI (GPVI), comprising at least one active [principle] principal that induces an irreversible inactivation or degradation of a GPVI collagen receptor on thrombocytes, wherein the medicament is in the form of a physiologically acceptable injection.

2. (Twice Amended) The medicament as claimed in claim 1, wherein the at least one active [principle] principal is an antibody.

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3. (Twice Amended) The medicament as claimed in claim 1, wherein the at least one active [principle] principal is monoclonal antibody JAQ1.

5. (Twice Amended) The medicament as claimed in claim 1, wherein the at least one active [principle] principal is humanized monoclonal antibody JAQ1.

6. (Twice Amended) A diagnostic agent for the determination of the expression rate of a collagen receptor GPVI, comprising at least one labelled antibody chosen from a monoclonal antibody and a polyclonal antibody, wherein the at least one labelled antibody is directed against a GPVI epitope, and wherein the diagnostic agent is in the form of a physiologically acceptable injection.

11. (Twice Amended) A method for producing a medicament against thrombotic diseases involving platelet collagen receptor glycoprotein VI (GPVI), comprising providing at least one active [principle] principal that induces an irreversible inactivation or degradation of a GPVI collagen receptor on thrombocytes, combining the at least one active principal with a physiologically acceptable carrier to form a physiologically acceptable injection medicament.

12. (Twice Amended) The method as claimed in claim 11, wherein the at least one active [principle] principal is a monoclonal antibody.

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13. (Twice Amended) The method as claimed in claim 11, wherein the at least one active [principle] principal is monoclonal antibody JAQ1.

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